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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,019	12/26/2001	Roland Henri Contreras	JAB-1521	5960

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EXAMINER

ALLEN, MARIANNE P

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/030,019

Applicant(s)

CONTRERAS ET AL.

Examiner

Marianne P. Allen

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) 2-9, 11-16, 23, 24, 29-48, 54 and 55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1, 10, 17-22, 25-28 and 49-53 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-55 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1, 10, 17-22, 25-28, and 49-53 in the response submitted 11/28/2003 is acknowledged.

Claims 2-9, 11-16, 23-24, 29-48, 54, and 55 and all sequences other than SEQ ID NOS: 285 and 286 set forth in claims 1, 10, 17-22, 25-28, and 49-53 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse with respect to these claims and with traverse **with** respect to the SEQ ID NOS. in the response submitted 11/28/2003.

Applicant elected the amino acid sequence of SEQ ID NO: 286 with traverse. While applicant did not particularly point out SEQ ID NO: 285, review of the specification indicates that this nucleotide sequence encodes the amino acid sequence of SEQ ID NO: 286. As such, both SEQ ID NOS: 285 and 286 have been examined. With respect to the other sequences set forth in the claims, applicant's arguments are not persuasive. Applicant has argued that the amendment to claim 1 provides a special technical feature linking all of the nucleic acid products; however, this limitation was not present in the original claims and as filed, the claims properly lacked unity. See lack of unity/restriction requirement set forth in Office action of 10/15/03. In addition, independent claim 17 has not been amended to contain the limitation added to claim 1. Claim 19 is directed to a sequence that hybridizes to the nucleic acid of claim 1. It is not required to have any particular expression level characteristics. Claims 49 and 53 are directed to a human homologue of the nucleic acid of claim 1. The human homologue is not

required to have any particular expression level characteristics. See also, new matter rejection set forth below.

Claim Objections

Claim 20 is objected to because of the following informalities: Claim 20 lacks a terminal period (“.”). Appropriate correction is required.

Claim Rejections - 35 USC § 101/112

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 10 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 10 does not indicate the hand of man and distinguish the claimed yeast or fungus from a product of nature. For example, SEQ ID NO: 285 is identified as a nucleic acid found in *Candida albicans*.

Claims 1, 10, 17-22, 25-28, and 49-53 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial, and credible asserted utility or a well established utility.

SEQ ID NO: 285 is a 1229 nucleotide DNA sequence from *Candida albicans*. It encodes the 409 amino acid sequence of SEQ ID NO: 286. (See Figure 2.) Table 1 on page 37 indicates that YPR102C (corresponding to SEQ ID NO: 285) is upregulated by a factor of 0.17 as a result of *Bax*-induced cell death (see page 32, lines 15-20, of the specification). No other information is provided.

Neither SEQ ID NO: 285 nor 286 have been disclosed as having any similarity to known sequences with known function. The particular pathway that SEQ ID NOS: 285-286 are involved with in the *Bax*-induced cell death is not disclosed. It is unknown how or why the upregulation is caused or what effect such upregulation has. The particular role of these sequences is not disclosed. As such, one would not know how to use these sequences in any specific and substantial capacity without further experimentation. Further characterization of the sequence with respect to its biological activity or function would be required.

Claims 1, 10, 17-22, 25-28, and 49-53 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial, and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

It is an invitation to experiment and would require undue experimentation to characterize SEQ ID NO: 285 and nucleic acids encoding SEQ ID NO: 286 with respect to its biological activity or function. No particular guidance or direction is provided.

Claims 1, 10, 17-22, 25-28, and 49-53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection and written description rejection.

Claim 1 has been amended to recite “wherein expression of said nucleic acid molecule is varied by a factor of 5 or more as a result of Bax-induced cell death.” While the specific nucleic acids set forth in the claim (e.g. SEQ ID NO: 285) were identified by this expression criteria, there is no disclosure or contemplation of all nucleic acids encoding the amino acid sequences as set forth in the claims (e.g. all sequences encoding SEQ ID NO: 286) having this expression level. There is no disclosure or contemplation of those nucleic acids having more than 70%, 80%, 90%, or 97% similarity or identity having this expression level. There is no disclosure or contemplation of functional equivalents, derivatives, or bioprecursors having this expression level. There is no disclosure or contemplation of functional fragments or complements having this expression level. Finally, the Bax-induced cell death is not disclosed or contemplated with respect to any assay but rather mouse Bax- α induced cell death in yeast by using DNA encoding mouse Bax- α in a particular yeast plasmid. The limitation introduced in claim 1 is more generic than this.

Even if this new matter rejection is overcome, claim 1 recites “functional fragment or complement thereof for the preparation of a medicament for treating diseases associated with yeast or fungi.” The specification does not identify any such functional fragments or complements. No nucleic acid medicaments for treating any diseases associated with any yeast or fungi are disclosed. The structural identity of these sequences is not described. Likewise, no “functional equivalent, derivative or bioprecursor” sequences are disclosed. (See also claim 17 and dependent claims.) Claims 49 and 53 are directed to human homologues. The structural identity of such homologues are not disclosed. One of ordinary skill in the art has been provided

with no criteria to determine if a particular sequence would be considered the human homologue. All of these sequences lack written description.

Claims 1, 10, 17-22, 25-28, and 49-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 17 are indefinite for reciting SEQ ID NOS. that are not elected and withdrawn. Only SEQ ID NOS: 285 and 286 are under consideration.

Claim 1 recites “encoding a functional equivalent, derivative or bioprecursor.” It is unknown from the specification what particular structural or functional characteristics define a functional equivalent, derivative or bioprecursor. See also claim 17.

Claim 1 recites “more than 70% similar, preferably more than 80% similar, ... most preferably more than 97% similar” and “more than 70% identical, preferably more than 80% identical, ... most preferably more than 97% identical.” It is unclear what level of similarity or identity is ultimately required by the claim, the lowest or highest percentage. See also claim 17.

Claim 1 recites “functional fragment or complement thereof for the preparation of a medicament for treating diseases associated with yeast or fungi.” It is unknown from the specification what particular structural or functional characteristics define a functional fragment or complement that could be used in this way.

Claim 10 is confusing in reciting “selected from the group consisting of ... or.” It appears that improper Markush language has been used.

Claim 17 is confusing in reciting “involved in a pathway for programmed cell death of yeast or fungi.” It is unclear if each of the nucleic acids encompassed by the claim (e.g. having particular levels of identity or similarity, those encoding a functional equivalent, derivative or bioprecursor) must have this characteristic. It is unclear what particular activity would meet the limitation of “involved in a pathway.”

Claim 18 is confusing in depending upon claim 16 which is a non-elected claim. Claim 16 is directed to a method of treating infection. This appears to be typographical error.

Claim 19 is confusing in reciting “selectively hybridizing.” It is unclear what degree of hybridization would meet this limitation.

Claims 26-27 are confusing in that the vector elements recited are not operably linked or in any way associated with the nucleic acid of claim 17. See also claims 50-51.

Claims 49 and 53 are confusing in reciting a “human homologue.” It is unclear what functional or structural characteristics define a human homologue. That is, must the sequence have a particular level of identity, similarity, or some other feature? In addition, claim 53 recites “human homologue of at least one of the nucleic acid sequences.” It is unclear what applicant intends by this language. Must the sequence have a particular level of identity, similarity, or some other feature to multiple sequences?

Conclusion

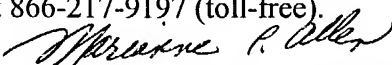
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712. The examiner can normally be reached on Monday-Thursday, 5:30 am - 1:30 pm.

Art Unit: 1631

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Marianne P. Allen
Primary Examiner
Art Unit 1631

4/19/04

mpa